PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, November 18, 2003, 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Chair Christine Ferguson (arrived late at 10:50 a.m. during staff presentation), Deputy Commissioner Susan Thompson as Acting Chair, Ms. Phyllis Cudmore, Mr. Manthala George, Jr., Ms. Maureen Pompeo, Mr. Gaylord Thayer, Jr., Ms. Janet Slemenda, Dr. Thomas Sterne, and Dr. Martin Williams. Mr. Albert Sherman was absent. Attorney Donna Levin was present as General Counsel. Deputy Commissioner Susan Thompson was also present.

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Acting Chair Susan Thompson announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A ½. In addition, Acting Commissioner Susan Thompson made the following announcement: New Business: A Staff Presentation entitled "Statewide Survey of Massachusetts Employers on Employee Based Health Insurance," by Maria Schiff, Policy Manager, Mass. Division of Health Care Finance Policy.

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The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Ms. Suzanne Condon, Assistant Commissioner, Bureau of Environmental Health Assessment; Ms. Gillian Haney, Director, Surveillance Program Manager, Division of Epidemiology and Immunization, Bureau of Communicable Disease Control; Dr. Paul Dreyer, Director, Division of Health Care Quality; and Ms. Joyce James, Director, Determination of Need Program.

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**RECORDS OF THE PU BLIC HEALTH COUNCIL MEETING OF SEPTEMBER 23, 2003:**

Records of the Public Health Council meeting of September 23, 2003 were presented to Council for approval. After consideration, upon motion made and duly seconded, it was voted (unanimously) [Chair Ferguson not present to vote] that records of the meeting of September 23, 2003 be approved.

**PERSONNEL ACTIONS:**

In a letter dated November 6, 2003, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of reappointments to the various staffs of Tewksbury Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted

(unanimously): [Chair Ferguson not present to vote] That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the reappointments to the various staffs of Tewksbury Hospital be approved for a period of two years beginning November 1, 2003 to November 1, 2005:

| **REAPPOINTMENTS:** | **STATUS/SPECIALTY:** | **MEDICAL LICENSE NO.:** |
|---|---|---|
| Kathleen Brady, MD | Active/Psychiatry | 60484 |
| Daniel Breslin, MD | Active/Psychiatry | 60138 |
| Shirish Desai, MD | Active/Internal Medicine | 40000 |
| Mithlesh Garg, PhD | Allied/Psychology | 168 |
| Judy Hurwitz, DPM | Consultant/Podiatry | 2150 |

In a letter dated November 10, 2003, Blake M. Molleur, Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of the reappointments of a physician and an oral surgeon to the consulting medical staff of Western Massachusetts Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the authority of the Massachusetts General Laws, Section 6, the following reappointments to the consulting medical staff of Western Massachusetts be approved:

| **REAPPOINTMENTS:** | **STATUS/SPECIALTY:** | **MEDICAL LICENSE NO.:** |
|---|---|---|
| Phillip Glynn, MD | Oncology/Hematology | 57384 |
| Alan Sampson, DMD | Oral Surgery | 10596 |

**PROPOSED REGULATIONS**:

**INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO THE HOSPITAL LICENSURE REGULATIONS (105 CMR 130.000) REGARDING THE DESIGNATION OF PRIMARY STROKE SERVICES:**

Dr. Paul Dreyer, Director, Division of Health Care Quality, presented the proposed amendments to the Hospital Licensure Regulations (105 CMR 130.000) Regarding the Designation of Primary Stroke Services. Dr. Dreyer noted the following:

Over the past several months, the Department has been working with clinicians, hospitals, and advocates to develop standards for designating Primary Stroke Services in hospitals that are equipped to rapidly triage and treat patents presenting with symptoms of acute stroke. These standards for voluntary designation are based on the nationally recognized consensus position outlines in "Recommendations for the Establishment of Primary Stroke Centers," which appeared in JAMA, June 21, 2000, Vol.283, No. 23, pages 3102-3109. Each year over 3500 Massachusetts citizens die from stroke. Stroke is the third leading cause of death in Massachusetts and a leading cause of disability.

Stroke is a type of cardiovascular disease that affects the arteries leading to and within the brain. There are two major types of acute stroke. Acute hemorrhagic stroke occurs when a blood vessel, which carries oxygen and nutrients to the brain, ruptures and causes bleeding into or around the brain. Acute ischemic stroke occurs when a blood vessel to the brain is blocked by a clot. An estimated eighty percent of strokes are ischemic. Historically, no effective treatment has been available for acute ischemic stroke. Clinical trials have established thrombolytic therapy as an effective treatment if administered within limited time parameters. Based on these clinical trials, the Food and Drug Administration approved the use of tissue-type plasminogen activator, a thrombolytic agent also know as t-PA, for patients with acute ischemic stroke if given with three hours of symptom onset. However, less than five percent of people with acute ischemic stroke receive thrombolytic agents within the recommended time frames. The American Heart Association and other clinical standard setting entities have recommended that Primary Stroke Services be established to ensure that clinically eligible patients are afforded the opportunity to receive this definitive care.

**Proposed Amendments to the Hospital Licensure Regulations:**

With the goal of improving the care and outcomes of acute ischemic stroke patients, the Department has drafted the attached proposed amendments to the hospital licensure regulations to establish standards for Primary Stroke Services. A hospital providing licensed emergency services may apply for designation. The standards include the following hospital requirements:

1) Creation of an Acute Stroke Team, with a physician director who has training and expertise in cerebrovascular disease,
2) Development and implementation of written care protocols
3) Availability of the service 24 hours per day, seven days a week
4) Development and implementation of effective communication with Emergency Medical Service personnel in the pre-hospital setting during the transportation of a patient with symptoms of acute stroke,
5) Rapid availability of neuroimaging and other imaging, electrocardiogram, laboratory and neurosurgical services
6) Continuing health professional education
7) Development and implementation of quality assessment and improvement programs and
8) Data collection, with submission of select data to a data center approved by the Department

Upon promulgation of the Primary Stroke Service Licensure Regulations, the Department will issue an advisory bulleting establishing the time targets, the data set and data centers referenced in the regulations. The Department will release the proposed amendments for public hearing and comment and return to the Council with a final recommendation.

**No Vote/Informational Only**

**INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 300.000: REPORTABLE DISEASES, SURVEILLANCE, ISOLATION AND QUARRANTINE REGULATIONS:**

Ms. Gillian A. Haney, MPH, Surveillance Program Manager, Division of Communicable Disease Control, and Ms. Suzanne Condon, MS, Assistant Commissioner, Bureau of Environmental Health Assessment, presented the Informational Briefing on Proposed Amendments to 105 CMR 300.000: Reportable Diseases, Surveillance, Isolation and Quarantine Regulations and noted in memorandum the following:

The purpose of this memorandum is to advise the Public Health Council of our intent to hold a public hearing on proposed amendments to 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation of Quarantine Regulations. The proposed amendments would authorize the Department to conduct surveillance (without requiring reporting) for certain diseases that are possibly linked to environmental exposures. In addition, the proposed amendments would update the regulations to add the emerging diseases Severe Acute Respiratory Syndrome (SARS) and Monkeypox to the list of reportable diseases and incorporate the latest federal recommendations for isolation and quarantine.

**Description of the Proposed Revisions to the Regulations**
**Background**

M.G.L. c.111.ss 1,3,5,6,7,94C, 109, 110, 110B, 111 and 112 outline the responsibilities of the local boards of health and the Department with respect to the reporting and control of diseases dangerous to the public health. M.G.L. c.111D, s 6 references clinical laboratories in reporting to the Department.

**Diseases Possibly Linked to Environmental Exposures**

M.G.L. c. 111, s 6, states: "The department shall have the power to define, and shall from time to time define, what diseases shall be deemed to be dangerous to the public health, and shall make such rules and regulations consistent with law for the control and prevention of such diseases as it deems advisable for the protection of public health." Consistent with this mandate, the Department is seeking to amend these regulations in part to permit surveillance only, without requiring reporting, for specific diseases that are possibly linked to environmental exposures. The specific diseases are: Amyotrophic Lateral Sclerosis (ALS), Aplastic Anemia, Asthma, Autism Spectrum Disorder (ASD), Multiple Sclerosis (MS), Myelodysplastic Syndrome (MDS), Scleroderma and Systemic Lupus Erythematosus. The basis for listing specific diseases possibly linked to environmental exposures for purposes of enhancing disease surveillance is further described below. The Department's Bureau of Environmental Health Assessment (BEHA) has the mission of investigating the occurrence of environmentally related diseases. As part of its mission, BEHA is often asked by legislators, local health officials, and community residents to conduct public health investigations where concerns exist regarding the possible contribution of environmental exposures to disease

clusters. Most recently, the Department was one of seven states to be asked by the U.S. Centers for Disease Control and Prevention (CDC) to develop and implement surveillance systems to track the occurrence of environmentally related diseases. BEHA has begun this important work, but since most of these diseases possibly linked to environmental exposures are not required to be reported to the Department, BEHA must have access to confidential health records held by hospitals, clinics, medical offices, and other health care providers in order to conduct these surveillance activities. As a result of the implementation of the recent HIPAA (Health Insurance Portability and Accountability Act) privacy regulations, a number of health providers have been reluctant to provide the Department access to medical records because of fears that they might violate HIPAA in not protecting the privacy of confidential medical information. Without clear legal authority to collect these records to date, BEHA has had to submit a detailed research protocol for review and approval to the Institutional Review Board (IRB) at each health care institution holding such records. This has been an extremely slow and arduous process to collect records for what CDC and the Department both believe is disease surveillance, not research. If surveillance data suggest that a more comprehensive research protocol is warranted, scientific protocols would be developed and BEHA would then seek appropriate IRB approvals.

The proposed amendments would facilitate the Department's mission by giving Department staff legal authority to access medical records and other information held by health care professionals in order to conduct disease surveillance for specific diseases that are possibly linked with environmental exposures. Specifically, this amendment would give the Department regulatory authority to access protected health information held by HIPAA covered entities without seeking individual patient authorization or approval by each institution's IRB based on the exemption in HIPAA that permits covered entities to disclose protected health information to public health authorities authorized by law to receive such information. Seeking authorization from each patient for disease surveillance activities would not only be infeasible, but also was not intended by the HIPAA privacy regulations. As previously noted, requests for access to records for research purposes is a very lengthy process and not appropriate for disease surveillance activities. The amended regulations would allow Department staff to have access to records to identify individuals with the specifically named diseases possibly linked to environmental exposures. However, the amendments would also add surveillance activities to the existing language that permits the Commissioner to add, on a time-limited basis, other conditions which are newly recognized, recently identified, or suspected as a public health concern.

## Conclusions

We are informing the Public Health Council that the Bureau of Communicable Disease Control and the Bureau of Environmental Health Assessment plan to hold a public hearing to receive comments on proposed amendments to 105 CMR 300.000. Adoption of the proposed regulations will allow BEHA to undertake surveillance of diseases possibly linked to environment exposures as requested by the CDC. It will allow the Department to continue to require the reporting of SARS; establish reporting

requirements for another emerging disease, Monkeypox; and incorporate the most recent federal recommendations for isolation and quarantine.

**No Vote/Informational Only**

**REGULATIONS:**

**REQUEST FOR FINAL PROMULGATION OF PROPOSED AMENDMENT TO DETERMINATION OF NEED REGULATIONS 105 CMR 100.000 GOVERNING APPLICATION FILING DAYS FOR INNOVATIVE SERVICES AND NEW TECHNOLOGY:**

Ms. Joyce James, Director, Determination of Need Program presented the Request for Final Promulgation to Determination of Need Regulations 105 CMR 100.000 Governing Application Filing Days for Innovative Services and New Technology. Ms. James said in part, "…The purpose of this memorandum is to request the Public Health Council's approval for final promulgation of the amendment to the Determination of Need Regulations 105 CMR 100.302, governing Filing Days for Applications and Amendments. Approval of the amendment will delay the filing day of applications for Neonatal Intensive Care Units (NICU), defined by the Department as an innovative service, until the first business day of August 2004. On September 23, 2003, the Council adopted an emergency amendment to the DoN Regulations105 CMR 100.302. This amendment, which delayed the filing day of applications for NICUs until the first business day of August 2004, was previously adopted by the Council as an emergency regulation on June 24, 2003. The September 23, 2003 emergency amendment was necessary to allow completion of the regulatory process, i.e., a public hearing must be held and final regulations submitted to the Council for adoption."

Ms. James continued, "A public hearing was held by Department staff on September 25, 2003, in the Public Health Council Conference Room, 250 Washington Street, Boston, MA. One person attended the hearing but did not testify. Comments were submitted by Drs. Laura Riley and Steven Ringer, of Partners Healthcare, Inc., supporting the amendment to delay the filing day of applications for NICUs until the first business day of August 2004. The comments indicated that the physicians were interested in working with the Department of Public Health to more fully understand and address the current need in Massachusetts for a maternal and newborn system of care. They also commented that in order for Massachusetts to continue its national leadership role in addressing policy and regulatory issues related to the provision of maternal and newborn care, state public health efforts must be updated and strengthened. The Department asks that this amendment be approved for final promulgation as presented today."

After consideration, upon motion made and duly granted, it was voted (unanimously) [Chair Ferguson not present to vote] to **approve the Request for Final Promulgation of Proposed Amendment to Determination of Need Regulations 105 CMR 100.000 Governing Application Filing Days for Innovative Services and New Technology changing the NICU filing date to the first business day of August 2004** ; that a copy

shall be sent to the Secretary of the Commonwealth; and that a copy is attached to and made a part of this record as **Exhibit Number14,771.** .

**NEW BUSINESS: STAFF PRESENTATION:**
**NO VOTE/INFORMATIONAL ONLY**

**"Statewide Survey of Massachusetts Employers on Employee Based Health Insurance", by Maria Schiff, Policy Manager, Massachusetts Division of Health Care Finance Policy**

Note – For the Record: Chair Ferguson arrived at 10:50 a.m., during this presentation.

Ms. Maria Schiff, Policy Manager, Massachusetts Division of Health Care Finance Policy, presented a report entitled "Statewide Survey of Massachusetts Employers on Employee Based Health Insurance." The data indicated monthly insurance premiums for both individual and family plans rose 17% from 2002 to 2003 for Massachusetts employers, with both employers and employees paying more to meet the increase. Workers also paid more in out of pocket co-payments for office visits, emergency department visits and prescription drugs. These are among the findings of a new statewide survey of private employers conducted by the Massachusetts Division of Health Care Finance and Policy. The survey is the Division's second, making information available for the first time on trends among Massachusetts employers in the area of health insurance costs, policies and benefits…Among the highlights of the DHCFP statewide survey are:

- Employer offer rate stayed steady in 2003 at 68%
- Employee take-up rate (employees opting to pick up coverage offered) stayed steady at 76% in 2003
- Mean total premium cost for individual plans rose 20% to $323 monthly from 2001 to 2003
- Mean total premium cost for family plans rose 20% to $852 monthly from 2001 to 2003
- Mean required employee contribution to family plans dropped slightly from 30% to 29% of total premium from 2001 to 2003 but since total premium rose, so obviously did absolute employee contribution
- From 2001 to 2003, co-payments increased for office visits, emergency room visits and pharmaceuticals

Discussion followed, in which Ms. Amy Lischko, HCFA participated from floor.

- Survey conducted by mail between June and September, 2003
- 884 employers responded, response rate 60%
- Survey included private sector establishments with more than one employee
- Second statewide survey, first conducted in 2001
- Slightly fewer employers offer their employees insurance in 2003 than in 2001.

- Large employers are more likely to offer their employees insurance than small employers.
- Fewer employers offer coverage to spouses and dependents in 2003 than in 2001.
- From 2002 to 2003, premiums for individual plans rose 17% on average.
- The employer contribution to total premium for individual plans dropped 6% on average from 2001 to 2003.
- The employee contribution to employer-sponsored individual plans increased 61% on average from 2001 to 2003.
- From 2002 to 2003, premiums for family plans rose 17% on average.
- The employer contribution to total premium for family plans remained constant at 71% from 2001 to 2003.
- The employee contribution to employer-sponsored family plans increased 28% on average from 2001 to 2003.
- From 2001 to 2003, median copayments increased for both MD office visits and ER visits.

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The meeting adjourned at 11:05 a.m.

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Christine C. Ferguson, Chair
Public Health Council

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